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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/823,429 | 04/12/2004 | Peter Miller | INA-10902/08 | 4021 |

25006 7590 03/15/2007
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| EXAMINER |
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MCCORMICK EWOLDT, SUSAN BETH

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| ART UNIT | PAPER NUMBER |
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1661

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/15/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/823,429

Applicant(s)

MILLER ET AL.

Examiner

S. B. McCormick-Ewoldt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-15, 17, 18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-15, 17, 18 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment of January 12, 2007 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant elected Group I, creatine monohydrate and dextrose, in the reply filed on July 11, 2005 is acknowledged.

Claims Pending

Applicant has added claim 21. Claims 1-5, 10-15, 17-18 and 21 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 10-15, 17-18 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention:

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In *re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to "cinnamon, or an extract of cinnamon or a derivative thereof" and "creatine or a derivative or a precursor thereof." Regarding derivatives

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and precursors, the specification does not define the term, but does indicate that it *includes*, i.e., is not limited to, chalcones, methyl hydroxyl chalcone polymer (i.e. MCHP) (page 7 of the specification) and creatine derivatives include creatine monohydrate and other hydrates, creatine esters, phosphorylated creatine, creatine pyruvate and precursors include glycocyamine or Guanidineacetic acid, arginine, glycine and methione (page 8 of the specification). It is equally clear that term encompasses an essentially unlimited genus. Given that the specification discloses only one cinnamon derivative, for example, chalcone, and a small number of creatine derivatives and precursors (see above), one of skill in the art would conclude that the specification fails to adequately describe the claimed genus.

There is insufficient written description to show that Applicant was in possession of “cinnamon, or an extract of cinnamon or a derivative thereof” and “creatine or a derivative or a precursor thereof” (emphasis added) capable of functioning in the claimed inventions. Given the disclosure of none of the claimed equivalents, that might be encompassed for use in the inventions of claims, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus’s.

Regarding derivatives and precursors, the specification does not define the term, but does indicate that it *includes*, i.e., is not limited to, chalcones, methyl hydroxyl chalcone polymer (i.e. MCHP) (page 7 of the specification) and creatine derivatives include creatine monohydrate and other hydrates, creatine esters, phosphorylated creatine, creatine pyruvate and precursors include glycocyamine or Guanidineacetic acid, arginine, glycine and methione (page 8 of the specification). It is clear that no examples are disclosed and no common structure or function has been established. Such as in Example 1 of the specification (page 10), only creatine monohydrate, creatine magnesium chelate and Cinnulin PF™ is disclosed in the composition. Accordingly, it is clear that one of skill in the art would conclude that the specification fails to adequately describe the claimed genus.

There is insufficient written description to show that Applicant was in possession of “or a derivative thereof.” The specification discloses chalcones, methyl hydroxyl chalcone polymer (i.e. MCHP) (page 7 of the specification) and creatine derivatives include creatine monohydrate and other hydrates, creatine esters, phosphorylated creatine, creatine pyruvate and precursors include glycocyamine or Guanidineacetic acid, arginine, glycine and methione (page 8 of the

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specification). The claims however, encompass the use of an essentially unlimited genus of derivatives. Given the limited disclosure and the unlimited number "or a derivative thereof," and "or derivative or a precursor thereof," one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus.

Claim Rejections - 35 USC § 103

Applicant's arguments, see pages 2-3, filed January 12, 2007, with respect to claims 1-5, 10-15, 17-18 and 21 have been fully considered and are persuasive. The rejection of claims 1-5, 10-15, 17-18 and 21 has been withdrawn.

Summary

No claim is allowed.

Correspondence

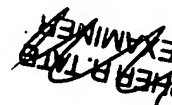
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme


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